AMCP Academy of Managed Care Pharmacy®

July 1, 2014

The Honorable Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

**RE: *CMS-1609-P*. Medicare Program; FY 2015 Hospice Wage Index and Payment Rate Update; Hospice Quality Reporting Requirements and Process and Appeals for Part D Payment for Drugs for Beneficiaries Enrolled in Hospice; Proposed Rule (42 CFR Parts 405 and 418)**

Dear Administrator Tavenner:

The Academy of Managed Care Pharmacy (AMCP) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule, *Medicare Program; FY 2015 Hospice Wage Index and Payment Rate Update; Hospice Quality Reporting Requirements and Process and Appeals for Part D Payment for Drugs for Beneficiaries Enrolled in Hospice; Proposed Rule (42 CFR Parts 405 and 418).* Specifically, AMCP provides comment on proposed rule §III.I, Solicitation of Comments on Coordination of Benefits Process and Appeals for Part D Payment for Drugs While Beneficiaries are Under a Hospice Election. AMCP encourages CMS to develop a hospice medication payment policy that ensures appropriate access to medications and other therapies to terminally ill Medicare beneficiaries who receive hospice and their caregivers and families. These policies should ensure that beneficiaries and their families should not be burdened with unnecessary requirements that may delay access to medications and hospice care.

AMCP supports CMS' efforts to improve and streamline the hospice benefit for 2015 by proposing several approaches and seeking feedback through a formal notice and comment period. However, this time period may not be sufficient to provide the most effective feedback on solutions from the industry because the most recent CMS guidance on coordination between and among hospice organizations, Medicare Part D prescription drug plans (PDPs), and pharmacies took effect on May 1, 2014.[1] Considering lags in processing time, stakeholders did not become aware of the extent of billing and access issues raised by the policy until several weeks after implementation of the guidance. CMS then published the proposed 2015 hospice rule on May 8, 2014, just as the stakeholders began discussing the issues posed by the guidance and considering potential resolution. AMCP also understands that CMS intends to issue additional guidance on the hospice payment policy. The stakeholders should be allowed sufficient time to review this guidance and provide comment before CMS finalizes suggestions in

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rulemaking for 2015. Given these circumstances, CMS could provide additional time to develop an effective approach for hospice medication coverage by either extending the notice and comment period or providing a separate notice and comment period to allow stakeholders sufficient time to consider all of the issues and provide reasonable suggestions.

AMCP is a national professional association of pharmacists and other health care practitioners who serve society by the application of sound medication management principles and strategies to improve health care for all. The Academy's more than 7,000 members develop and provide a diversified range of clinical, educational and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit.

As mentioned previously, AMCP is currently working with stakeholders representing hospice organizations, hospice beneficiaries, hospice physicians, pharmacists and pharmacies, long-term care, and PDPs to clarify issues regarding whether medications are related or unrelated to the beneficiaries' terminal illness and thus whether a certain medication should be covered by the Medicare Part A hospice benefit or Medicare Part D. AMCP appreciates CMS' efforts to clarify coverage requirements and to implement clearer policies regarding whether a medication is related or unrelated to a terminal illnesses in its proposed rule. However, any changes suggested by this proposed rule would not become effective until 2015. AMCP understands that issues presented by CMS' most recent policy clarification on this subject effective on May 1, 2014, are creating substantial difficulties to access to care, and thus Medicare should suspend implementation of the current policy until CMS and the affected stakeholders implement a more workable and effective solution.

In determining whether a medication is covered by a hospice formulary, and not relying simply on determinations of "related" or unrelated" to the terminal illness, AMCP supports the establishment of review standards for hospice formularies that are similar to Medicare Part D requirements, including considerations for robust formularies and specific examples of medications that do not relate to the terminal illness and thus should not be covered by the hospice benefit. For example, further clarity is necessary to establish:

- whether medications prescribed for a chronic condition prior to hospice election are excluded from hospice coverage because they are not related to management of symptoms associated with the terminal illness;
- whether medications taken for management of illnesses that develop after hospice election would be covered by Medicare Part A or Part D;
- timeliness of hospice responses to PA notices from PDPs, and standards for PDPs to review documents sent by the hospice to the PDP;
- whether a beneficiary is deemed to have creditable coverage for Medicare Part D during a hospice stay or whether the individual must re-enroll in the program after revocation of hospice coverage; and,
- consider issues related to the level necessary for coordination between the PDP and hospice if hospice coverage is denied.

These issues were not included or suggested in the proposed rule, but should be included in a formal notice and comment period. Not only would formulary review provide clarity, it would also allow hospice providers to spend their time on patient care rather than providing written clinical justification when a medication is related to the terminal illness.

AMCP is also concerned that the CMS proposed policy for the coordination of benefits and communications relies on outdated and inefficient methods, including verbal discussions and facsimile transmissions. To effectively implement the hospice policy would require a more robust electronic health records (EHR) system, which is not accessible to hospice settings, PDPs, pharmacists or pharmacies. In a provision of the propose rule related to measure development, CMS acknowledges that more robust adoption of EHRs for hospice providers is in development. For PDPs and pharmacies, the adoption of EHRs is not imminent, and thus an effective solution will be difficult to achieve in the short term. CMS' own communications to hospice providers and other entities regarding beneficiaries' enrollment and disenrollment in hospice continue to be problematic and often delayed or inaccurate. CMS' final policy should work to provide more effective and timely communications among the affected entities and not place beneficiaries and their families in a position that requires a lengthy administrative process to receive access, coverage, and approval. Therefore, as stated above, CMS and its contractors should rely on formulary parameters rather than individual clinical case studies to determine whether a medication is covered by the Medicare Part A hospice benefit or by Medicare Part D.

CMS proposes several solutions for communication among the hospice organization and the PDP. Both solutions rely on direct communication with a beneficiary or beneficiary representative to achieve, and both present other shortcomings that prohibit feasibility. One solution would allow the provider to initiate the notification of a potential hospice beneficiary to the PDP. This solution would require that the hospice organization verify the beneficiary's Medicare Part D coverage by requesting the card from either the beneficiary or the beneficiary's representative. As mentioned previously, it is neither feasible nor appropriate to request this information from the beneficiary or their representative during hospice care. Furthermore, these type of requests could also delay access to coverage and necessary medications. CMS should find an approach where the hospice organization receives direct access to information about Part D coverage without relying on the beneficiary or representative.

Another proposed suggestion is to require the PDP to verify hospice coverage and then communicate with the pharmacy whether the beneficiary is covered by Part A or D at the point of sale. This, too, will likely result in unnecessary delays or denials of care because PDPs often do not receive the transaction reply report in a timely manner, and thus the plan could not accurately verify all hospice beneficiaries. Therefore, the problem is that beneficiaries could be denied access to the medication at the pharmacy or in a long-term care facility. This solution also requires contact by the beneficiary or the beneficiary's representative to the PDP to receive a coverage determination. As stated previously, hospice beneficiary or representative involvement in this process is neither appropriate nor feasible. Given the inadequacies of the current suggestions and processes, CMS should allow more time for stakeholders to develop better solutions not considered during this rulemaking.

CMS' proposal and previous guidance documents discuss the use of a review process by an independent review entity (IRE) contracted with CMS to manage disputes involving hospice providers and PDPs. However, this process has not been clearly defined in CMS' guidance documents or the proposed rule. Issues that remain unresolved in the proposal for IREs include: rules related to the hearing process, the enforcement process for final determinations; and any fees associated with this process. This new process requires more clarity and should not be

considered in sub-regulatory guidance but, rather, through a formal notice and comment period so stakeholders can provide input based on their experiences. A formal notice and comment period would ensure that this issue has the proper force and effect of law and CMS oversight. Given that CMS did not include this information in the proposed rule, AMCP recommends that CMS either extend the timeframe for responses to the proposed rule or that CMS propose a separate rule to consider these issues.

AMCP appreciates CMS' efforts to clarify medication coverage for hospice beneficiaries. CMS' release of proposed rulemaking is a step to ensure clarity and regulatory oversight, but significant gaps remain in administration and enforcement issues. Therefore, AMCP reiterates that CMS should allow more time to receive constructive suggestions from the stakeholders before implementing additional requirements that create more confusion.

Thank you for considering AMCP's comments. AMCP looks forward to continued improvement in this area to ensure that terminally ill hospice beneficiaries receive access to necessary and appropriate medications in a timely manner. If you have any questions, please contact me at 703-683-8416 or erosato@amcp.org.

Sincerely,

Edith Rosato, RPh, IOM
Chief Executive Officer

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[1] McKutcheon TM, Wilson L. Part D for Drugs for Beneficiaries Enrolled in Hospice. CMS; March 10, 2014. http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/Downloads/Part-D-Payment-Hospice-Final-2014-Guidance.pdf. Accessed June 30, 2014.